Scaling up the univocal identification of medicines for patient safety, better healthcare and public health

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INTRODUCTION

The UNICOM project’s main objective is to accelerate and scale up the implementation of the suite of standards of the International Organization for Standardization for the Identification of Medicinal Products (ISO IDMP) throughout the healthcare ecosystem.

The IDMP ensures that any medicine, and what it contains, can be accurately identified anywhere in Europe and indeed globally.

Unique identification is the foundation and the core of an interoperable and dynamic ecosystem (section 3) dedicated to better patient safety and better healthcare for all.

The ISO IDMP standards cover the core identifiers for a medicinal product, notably a common format for the Medicinal Product Identifier (MPID), the Medicinal Product Package Identifier (PCID), and for a global Pharmaceutical Product Identifier (PhPID).

1.1 Solving issues in healthcare and public health

Many critical issues arising from the inaccurate identification of medicinal products can largely be solved through the use of the ISO IDMP standards suite, which helps to provide complete and accurate data about a medicinal product throughout its life cycle across the whole ecosystem. Example use cases are: fighting drug falsification, avoiding negative drug-drug interactions in medicine prescription and dispensing helping physicians and pharmacists make substitution decisions (if their first choice of product is not available), helping prescribing decision support systems to perform drug-allergy, drug-condition checking on any medicine the patient is taking or might newly take, irrespective of the European country from which the medication list was populated, as well as supporting the reporting of adverse events (pharmacovigilance).

1.2 The European Health Data Space

UNICOM’s work has been undertaken at an ideal point in the in the evolution of EU policy, which is well aligned to the wider use of IDMP standards. The future European Health Data Space (EHDS) Regulation will provide a legal framework which requires Member States to use standardised Electronic Health Record
1.3 UNICOM is calling for action

Meeting the market authorisation requirements and leveraging the power of standardised identification of medicines require significant change along the full length of the pharmaceuticals value chain. The UNICOM project has assessed and addressed many of the changes that will be needed and has provided tools and baseline analyses to do so. However, significant action is needed from all stakeholders in the medicinal products value chain. UNICOM calls upon all stakeholders, and in particular on state actors to come together to address the key challenges related to interoperability and international co-operation, and focus specifically on:

1. Creating an interoperable and increasingly integrated medicinal product data ecosystem
2. Leveraging the power of the Pharmaceutical Product Identifier in the international context
3. Using ISO IDMP standards implementation as a key enabler of the European Health Data Space.

1.4 Following sections

In the next sections, UNICOM achievements are described in more detail (section 2), followed by an in-depth exploration of interoperability issues at stake (section 3). Global – including transatlantic – collaboration is then covered (section 4). We then look at the way forward, with a focus on the future European Health Data Space (EHDS) (section 5). Calls-to-action are made in the appropriate sections.

2 UNICOM ACHIEVEMENTS IN SUMMARY

The UNICOM partners have opened and developed the conversation between key stakeholders on medicinal product identification. They have worked together to break down silos between the actors in the medicinal product value chain to build a strong consensus: medicinal product data interoperability and governance is a shared responsibility.

2.1 Scaling up IDMP implementation

UNICOM partners have worked together on transitioning to ISO IDMP implementation. They have collaborated with the European Directorate for the Quality of Medicines & HealthCare (EDQM) on the latest standard for dose forms, and with World Health Organization’s Uppsala Monitoring Centre (UMC) on its systematic methodology for PhPID generation. Impact of the choice of specific terminologies for use (EHR) systems, electronic prescription and dispensation records which conform to the European EHR Exchange Format (EHERxF) (section 5.1). The EHDS Regulation use data of both within and across EU borders, recognising that data must be Findable, Accessible, Interoperable and Reusable (FAIR).

With respect to the data identifying medicinal products, the IDMP standards go a long way towards making such data FAIR. The revision of the Pharmaceuticals legislation, will drive greater use of digital formats for submission of Marketing Authorisation dossiers, as well as will encourage the adoption of electronic patient information leaflets. Adverse event reporting tools have since long required the use of standardised medicinal product identification data, and indeed EMA EU IDMP Implementation Guide (EU IG) requires the use of ISO IDMP compliant data when new submissions for Marketing Authorisation are made.

2.2 Sandbox, educational resources and implementation guides

UNICOM partners have produced databases of sample products in IDMP format from which partners have been able to learn. UNICOM has implemented a server (UNICOM IDMP server) to store and evaluate IDMP conformat product datasets, which provides a “sandbox” for pilots.

UNICOM partners have also developed educational resources for the developers of Electronic Health Record (EHR) and pharmacy systems, to help them adapt to the use of ISO IDMP standards. The needs of healthcare professionals and patients have been addressed through the development of a patient facing app that offers ISO IDMP-enabled function related to their medication. They will have a particular application when a patient travels to another country in which a physician or pharmacist needs to substitute a product that is not available in the visited country.

UNICOM has not developed new interoperability assets but has worked closely with HL7 as it has developed a FHIR specification for IDMP conformant medicinal products. This UNICOM Interoperability Guide is published by HL7 in open access. UNICOM partners contributed to the implementation guidelines based on FHIR Release 5 (FHIR RS) published on the EMA website. A transatlantic Community of Expertise with participants from across the globe has emerged. It has been engaged in all progress made during the project lifetime. Consequently, the EU/EEA is now considered as the world laboratory for ISO IDMP implementation.

2.3 Enchancing cross-border healthcare services

UNICOM partners actively foster a close collaboration with the eHealth Network (eHN) and MyHealth@EU communities to drive the adoption of ISO IDMP within the services already in routine operations, which allow ePrescriptions (eP) / eDispensations (eD) and Patient Summaries (PS) to be exchanged in a secure and interoperable way among the participating countries in the EU. The close collaboration yielded significant results, such as the improvement of eHN guidelines for PS and eP/eD services, incorporating recommendations for the adoption of ISO IDMP and EMA SPOR data models and code systems.

Additionally, two change proposals were co-created with these key stakeholders and successfully accepted by Member States. These change proposals have paved the way for the future incorporation of IDMP identifiers. They also promoted improvements in describing medicines, encompassing aspects such as complex packaging, diverse representations of dose forms and strengths, and the identification of prescribed and dispensed medicinal products through distinct identifiers.

Due to the unavailability of IDMP identifiers, MyHealth@EU is not yet promoting the full implementation of ISO IDMP, it aims to utilise the ISO IDMP data model and EMA SPOR value sets to enhance the services and enable Member States to submit their data in a simplified yet standardised format. It is pertinent to acknowledge that even if a Member State cannot provide those data, they can still access the services, with the additional attributes and layers of information remaining optional for each respective country.

A PhPID uniquely identifies a pharmaceutical product by its substance, dose form and strength and may reside in each country’s medicinal product dictionary. A global PhPID can be calculated by the UMC. The PhPID itself is not one of the Project deliverables but UNICOM’s understanding is that PhPID is automatically generated making use of building blocks, such as substances. Two aspects that are relevant here are data cleansing as well as patterns for generating PhPIDs. It was observed by partners that PhPID is still not part of the EMA EU IDMP implementation in the EU. However, within the consortium NCA network, there has been significant progress on the usage of structured data elements based on EMA Substances, Products, Organisations and Referentials (SPOR) terminology.

cases extensions has been documented. Approaches to support National Competent Authorities (NCAs) in their legacy conversion work have been proposed.

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2.4 The new EMA electronic application forms and European Substance Database

Together with the European medicines regulatory network (EMRN), a new tool for creating ISO IDMP compliant application forms has been developed and a first release was launched for variations of centralised products. With this tool, IDMP compliant data will be available right from the start of the registration process.

A scientific substance database, the European Substance Registration System (EU-SRS) with ISO-IDMP compliant structured substance data was established to ensure unique and harmonised coding of substances. This high-quality substance database including their molecular structure allows its use in Big Data approaches. The data were harmonised with FDA Substance data (e.g., Chemicals) in the Global Substance Registration System (G-SRS) taking European legislation into account. The substance database was finalised by UNICOM together with the EMRN and has been handed over to EMA for hosting and maintenance of the system; the maintenance of the substances data in EU-SRS is the responsibility of the Substance Validation Group (SVG) of the Heads of Medicines Agencies (HMA). UNICOM members in particular have increased data quality based on the integration of SPOR terms. This in particular relates to Substance, Organisations, and Referentials.

The 11 participating NCAs have made significant progress in IDMP implementation in their national systems either by refactoring or building completely new IDMP compliant national databases. The NCAs continuously shared best practises, experiences and knowledge which is documented and made publicly available on the UNICOM website. This material can be used as training material for continued ISO IDMP implementation in EU/EEA NCAs and is open for use by other relevant stakeholders.

An overview of selected achievements is presented in the following figure. For further information, please refer to the UNICOM website, in particular under Resources.

Impact on Processes
- Gap Analysis of Existing and Need for New Standards and Profiles
- EU-SRS Implementation and going live
- DADI – Electronic application forms
- IDMP implementation on National level
- Contributions in eHDSI Waves 6 and 7 (2022-2024)
- IDMP Coding Principles and Guidance for ICsRs
- Implementation guidelines for use of IDMP within MPD

Resources and Assets
- IDMP in a capsule
- Minimum Attribute List and Pilot Product List (PPL)
- UNICOM FHIR IDMP server, UNICOM FHIR IG, and IDMP product browser for test and reuse
- Smart Substitution Component and Patient Facing App

Knowledge exchange
- Community of Expertise
- Trans-Atlantic exchange and workshops
- NCA Best Practice exchanges
- Contribution to Research papers

3 ENSURING INTEROPERABILITY

Interoperability is best defined as “the ability of different information systems, devices, and applications (systems) to access, exchange, integrate, and cooperatively use data in a coordinated manner, within and across organisational, regional, and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally”. Technical and semantic interoperability is usually the central focus when discussing interoperability, but it is also important to consider the different layers to create a truly interoperable ecosystem: legal/regulatory, policy, care process, information, applications, and infrastructure need all to be considered as described in Refined eHealth European Interoperability Framework (ReEFI).

3.1 Creating the foundation of an interoperable data ecosystem

UNICOM envisions interoperability across the value chain with the use of trusted high-quality data. To make use of the data within the eHealth sector, both locally and on a European level, collaboration between NCAs and eHealth organisations is getting increasingly important.

The principle of interoperability states that data is created with the objective in mind that it needs to be used by other systems downstream; this implies that data needs to conform to standards that are influenced also by users that do not play a role at the source of the data.

Medicinal product data in the broad sense, as required for the safe use of medication, does not originate at the point of care, in an EHRS system. The origin of medicinal product data comes from the marketing authorisation holders of medicinal products. Therefore, UNICOM has focused on e.g. ISO IDMP compliant standards for the electronic application forms (eAF) for submission of applications for both new medicinal products and variations of medicinal products. The move towards requiring ISO IDMP compliance in all new regulatory submissions for Marketing Authorisation is a huge step towards building a reliable medicinal product data.

EHR systems have not been designed with the objective of cross-border or secondary use of the data. They are serving, and should be serving, the needs of the delivery of healthcare to patients by teams of healthcare professionals within a healthcare provider organisation. Solving the problem of interoperability of medicinal products data at the source is essential for EHDS to work as a federated system with “downstream” use of medication data and also personal health data.

With the principle of interoperability across the value chain, it is recognised that the source of data elements within one data set may well be spread across many different organisations, that are part of the value chain. The full IDMP landscape illustrated by UNICOM partners identifies the value chain for medicinal products with a direct impact for all organisations involved in the medicinal product lifecycle.


Figure 2: Overview of selected UNICOM achievements

Figure 34: The Medicinal Product Data Value Chain according to UNICOM
### 3.2 Better use of medicinal product identification

In most countries, information about medicinal products with a marketing authorisation is published by the NCA in a public registry. If or how this data is used by the eHealth applications (for example, for ePrescription) varies a lot across different countries. It is important therefore to report and demonstrate the efficiency gains from reusing consistent data between European and national systems.

The benefit of using ISO IDMP at national level, i.e., the value of using standardised identification, is demonstrated in cases where different medicinal product identifiers are used in regulatory processes for distribution and reimbursement. Many countries using multiple identifiers often exploit a virtual product layer on top of product identifiers. In these cases, ISO IDMP offers an important opportunity to both creating a national ecosystem and making it interoperable with other EU countries.

Mapping between terminologies is needed and SPOR RMS can be used as a source for retrieving mapping information. In UNICOM, a mapping from EDOM to SNOMED CT dose forms has been performed. Moreover, both EDOM and SNOMED CT dose form descriptions are based on the same ISO standard, and hence very similar. It is thus essential to reuse and maintain existing mapping information (SPOR RMS) to avoid additional effort.

Data quality and consistency are essential prerequisites for effective and efficient data sharing. In UNICOM's view, the trusted source of quality medicinal product data are the NCA, even though data comes from the MAH (Marketing Authorisation Holder). Hence, the national contact points for eHealth (NCPEH) should base their work on the transformation of local medication information into the “pivot document” to be shared in the cross-border MyHealth@EU infrastructure. This transformation is based on trusted and interoperable data provided by the NCAs and EMA; this will guarantee that data can be trusted and that the infrastructure which makes the data available is maintained. Wide and consistent ISO IDMP implementation is a key enabler for the upcoming EHDS, allowing all actors to use trusted and harmonised data on medicinal products, which will in turn contribute to patient safety.

A key condition for enabling and maintaining interoperability of the value chain is the creation of an interoperable data ecosystem and its multi-stakeholder governance. IDMP offers Member States a unique opportunity to further develop the value chain and better integrate the different actors using medicinal product data.

### ISO IDMP

ISO IDMP is a set of international standards which the United States Federal Drug Administration (FDA) is also implementing. It is however important to highlight that IDMP is a data model and does not include terminologies, which means that EU and US data will not automatically be interoperable after implementing ISO IDMP. However, it does demand creating similar concepts for medicinal products, which means that identification and comparison of products becomes a lot easier. The Pharmaceutical product Identifier (PhPID) has the potential to associate medicinal products of similar composition in different countries using the same terminology by representing information about substance, dose form and strength at different levels of precision or aggregation. It is therefore a very powerful concept to ensure global alignment.

UNICOM has supported the discussions around the PhPID role and impact with all actors of the value chain and organised several working sessions bringing together key stakeholders on both sides of the Atlantic. Several world-wide pilots were conducted under the supervision of WHO-UMC, focusing e.g., on challenges regarding dose form and mapping to regional terminologies; identifying several issues for unique identification of substance and expression of strength. This resulted in proposed actions for updates of the ISO IDMP standards and continued work on best practices and business rules.

UNICOM has been in contact with the Global IDMP Working Group (GIDWG) created in October 2021. GIDWG started as a collaboration between FDA, WHO-UMC, and EMA, but is gradually expanding its scope of stakeholders. GIDWG has since then been working on five additional projects to support the PhPID production: Global Substance ID, Global Dose Form Identifier, Strength Definition Identifier, HL7 FHIR for IDMP and a Global PhPID Operating model.

The operational model for both query and assignment of global PhPIDs, through a service provided by WHO-UMC, has been successfully tested during a series of HL7 FHIR Connectathons, supported by the UNICOM project. Several actors active within UNICOM believe that the recognition of WHO-UMC as the official lead in the creation and maintenance of the global WHO-UMC PhPIDs, as well as Global WHO-UMC Substance IDs, could be a key milestone to progress towards global alignment.

The creation of a repository of global identifiers for national medicinal products (PhPIDs) by WHO-UMC provides a sandbox to take appropriate decisions on PhPID management. The ISO IDMP pharmaceutical product identifier (PhPID) business rules are defined in the standards. The used terminologies for data input differs across regions and the anticipated use cases.

Actual operational use of these PhPID services, whether European- or global, or in regulatory and clinical practice, depends on the incorporation of specific current medicinal product data in the new ISO IDMP

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**Figure 4: Five IDMP-compliant Unique Product Identifiers**

- **PHPID**
  - Pharmaceutical Product ID
- **MPID**
  - Medicinal Product ID
- **SID**
  - Substance ID
- **PCID**
  - Package ID
- **BAIDs**
  - Unique Product Identifiers

2: It was observed by UNICOM partners that PhPID is still not part of the EMA EU IG of ISO-IDMP implementation in EU and there is no clear business case for the use of PhPID in Europe. However, there has been significant progress on the usage of structured data elements based on EMA SPOR terminology.
5 SUSTAINABILITY AND WAY FORWARD

5.1 The EHDS and EEHRxF

UNICOM has established tight links with the eHealth Network working groups to support cross-border prescription leading to more mature ISO IDMP compatible specifications and solutions to previously identified problems. This is critical in the context of the roll out of the future European Health Data Space (EHDS) for which a wide and consistent implementation of ISO IDMP is key in allowing all those using the EHDS to use trusted and harmonised data on medicinal products.

The European EHRSfX to whom the EHDS Regulation makes direct reference, already includes direct references to IDMP and its implementation in Europe. These are present in both Patient Summary and ePrescription/eDispensation services. UNICOM calls upon its international partners to continue to enlarge the support for the exploitation of the PhPID, developing reference implementations for using PhPIDs in clinical decision support and other clinical use cases.

5.2 Impact on healthcare systems

Governance of the utilisation of the ISO IDMP standards within the European health systems needs to be undertaken actively at Member State and EU level, in order that the global perspective to guarantee maximum added value can be achieved in due course. Decisions should be taken based on collected knowledge and documenting possible scenarios.

An ambitious integrated workplan considering the whole value chain with clear operational objectives and deadlines needs to be drafted and discussed. Sustainability will be greatly supported by the EMA EU IG and further development of the secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the EU, the EMA Product Lifecycle Management Portal (EMALPLM) should be supported as high priority.

UNICOM calls upon the EU and Member States to urgently consider the use of European structural funds and/or other financial channels to support Member States accelerating their IDMP transformation journey. Further support initiatives to develop the new skills and knowledge needed for the transition. Propose a continuous monitoring process with sharing of best practice examples and twinnings to measure progress towards IDMP compliance.

5.3 Outlook

The European Commission Reviewers’ Report from February 2023 highlighted that UNICOM is a strategic project which has delivered exceptional results with significant immediate impact and outcomes with potential long-term impact.

The reviewers underlined that the project successfully brought together stakeholders from all relevant sectors of the European medicinal product ecosystem to drive the harmonised identification of medicines throughout Europe. National Competent Authorities play a central role in achieving a univocal drug identification system, essential for secure cross-border data exchange and the delivery of cross-border Patient Summary, ePrescription and eDispensation services. UNICOM’s potential impact is substantial, as it aims to facilitate health data exchange within the European Union while also contributing to additional domains including clinical research and pharmacovigilance.

To facilitate the necessary data provision, all NCAs must implement IDMP standards, including robust linkages to the European Medicines Agency’s master data management for Substances, Products, Organizations, and Referential (SPOR). Ensuring effective collaboration and shared responsibilities among NCAs, EMA, national eHealth agencies and other relevant authorities is pivotal, bearing direct implications for policy formulation and proactive engagement of public authorities across Europe.
Based on the excellent outcomes, a follow-up initiative is uniquely positioned to drive further deployment and scale up and address areas for improvement. It will actively seek to strengthen collaboration with the European Medicines Agency, fostering a more cohesive partnership to advance shared objectives of scaling up IDMP standards deployment to:

1. Enhance digitalisation in the medicinal product lifecycle,
2. Contributing to patient safety, improving efficiency, and boosting innovation.
Project acronym: UNICOM

Project full title: Up scaling the global univocal identification of medicines in the context of Digital Single Market strategy

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